

Application No.: 10/074,272
Amendment and Response dated March 29, 2005
Reply to Office Action of January 4, 2005
Docket No.: 1199-4
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Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-53 (cancelled)

Claim 54 (currently amended): A process for making a film having a substantially uniform distribution of components comprising:

- (a) combining a water-soluble polymer component and polar solvent to form a matrix with a uniform distribution of said components;
- (b) forming a film from said matrix by feeding said film onto a surface having top and bottom sides; and
- (c) drying said film by feeding said film onto a surface having top and bottom sides; said bottom side of said surface being in substantially uniform contact with a water bath at a temperature sufficient to dry said film.

Claim 55 (original): The process of claim 54, wherein said water bath is temperature controlled.

Claims 56-61 (cancelled)

Claim 62 (previously presented): The process of claim 54, further comprising the step of adding an active component to said matrix of step (a).

Claim 63 (previously presented): The process of claim 54, wherein said film is ingestible.

Claim 64 (previously presented): The process of claim 54, wherein said drying step maintains a non-self-aggregating uniform heterogeneity of said components throughout said film.

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Claim 65 (previously presented): The process of claim 54, wherein said film is flexible when dried.

Claim 66 (previously presented): The process of claim 54, wherein said film is self-supporting.

Claim 67 (previously presented): The process of claim 62, wherein uniform distribution determines the amount of active material component per area.

Claim 68 (previously presented): The process of claim 62, wherein a specific amount of the active material component may be obtained from said film by cutting said film to a predetermined size.

Claim 69 (previously presented): The process of claim 54, wherein said drying of said film occurs within about 10 minutes or fewer.

Claim 70 (previously presented): The process of claim 54, wherein said film includes a top side and a bottom side and said drying includes drying said bottom side first.

Claim 71 (previously presented): The process of claim 70, wherein said drying includes applying heat to said bottom side.

Claim 72 (previously presented): The process of claim 54, wherein said polar solvent is a combination of water and a polar organic solvent.

Claim 73 (previously presented): The process of claim 54, wherein said polar solvent is water.

Claim 74 (previously presented): The process of claim 54, wherein said polar solvent added in step (a) has a weight percent of at least about 30%.

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Claim 75 (previously presented): The process of claim 54, wherein said drying of said film reduces the weight percent of said polar solvent to about 10% or less.

Claim 76 (previously presented): The process of claim 54, wherein said drying of said film reduces the weight percent of said polar solvent to about 8% or less.

Claim 77 (previously presented): The process of claim 54, wherein said drying of said film reduces the weight percent of said polar solvent to about 6% or less.

Claim 78 (previously presented): The process of claim 62, wherein said active component is a member selected from the group consisting of medicaments, flavors, fragrances, enzymes, preservatives, sweetening agents, colorants, spices, vitamins, and combinations thereof.

Claim 79 (cancelled)

Claim 80 (previously presented): The process of claim 54, wherein said polymer is a cellulose derivative.

Claim 81 (currently amended): The process of claim 7954, wherein said water soluble polymer is a member selected from the group consisting of hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, polyvinylpyrrolidone, carboxymethyl cellulose, polyvinyl alcohol, sodium alginate, polyethylene glycol, xanthan gum, tragancanth gum, guar gum, acacia gum, arabic gum, polyacrylic acid, methylmethacrylate copolymer, carboxyvinyl copolymers, starch and combinations thereof.

Claim 82 (cancelled)

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Claim 83 (previously presented): The process of claim 54, wherein said film has a thickness of greater than about 0.1 mils.

Claim 84 (previously presented): The process of claim 54, wherein said film has a thickness of about 10 mils or fewer.

Claim 85 (previously presented): The process of claim 54, wherein said film has a substantially uniform thickness.

Claim 86 (previously presented): The process of claim 62, wherein said film is divided into dosage forms of substantially equal dimensions.

Claim 87 (currently amended): The process of claim 86, wherein each of said dosage forms contains a substantially equal amount of said active component.

Claim 88 (previously presented): The process of claim 86, wherein said dosage forms contain an amount of said active that varies about 10% or less among said dosage forms.

Claim 89 (previously presented): The process of claim 54, wherein said drying step comprises forming a visco-elastic structure.

Claim 90 (previously presented): The process of claim 54, wherein said drying step achieves a film of substantially uniform thickness and component distribution.

Claim 91 (new): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) combining an edible polymer component and a polar solvent to form an edible matrix with a uniform distribution of said components;

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- (b) forming a wet film from said matrix;
- (c) providing a surface having top and bottom sides;
- (d) feeding said film onto said top side of said surface; and
- (e) forming a self-supporting edible film by applying hot air currents to said bottom side of said surface with substantially no top air flow to dry said film.

Claim 92 (new): The process according to claim 91, further comprising the step of adding an active component to said matrix of step (a).

Claim 93 (new): The process according to claim 92, wherein said active component is taste masked.

Claim 94 (new): The process according to claim 91, wherein said wet film has a thickness of at least about 30 μ m.

Claim 95 (new): The process according to claim 91, wherein said wet film has a thickness of at least about 500 μ m.

Claim 96 (new): The process according to claim 91, wherein said wet film has a viscosity of about 400 cps to about 100,000 cps.

Claim 97 (new): The process according to claim 91, further comprising the step of removing said self-supporting film from said surface.

Claim 98 (new): The process according to claim 97, further comprising the step of dividing said self-supporting film into individual dosage forms of substantially equal dimensions.

Claim 99 (new): The process according to claim 98, further comprising the step of packaging each of said individual dosage forms.

Claim 100 (new): The process according to claim 91, wherein said self-supporting film is formed in conjunction with a removable backing.

Claim 101 (new): A process for making a self-supporting, edible film dosage unit having a substantially uniform distribution of components comprising:

- (a) providing a wet matrix having a uniform distribution of edible components, said components comprising a polymer component, an active component and a polar solvent;
- (b) forming a wet film from said wet matrix;
- (c) forming a self-supporting edible film by applying radiant energy selected from the group consisting of air currents, microwaves, infrared and combinations thereof, to said film to dry said film; and
- (d) dividing said self-supporting film into dosage forms of substantially equal dimensions, wherein each of said dosage forms is compositionally equal.

Claim 102 (new): The process according to claim 101, wherein each of said dosage forms has substantially the same mass.

Claim 103 (new): The process according to claim 101, wherein each of said dosage forms has substantially the same thickness.

Claim 104 (new): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

- (a) providing a wet matrix having a uniform distribution of edible components, said components comprising a polymer component and a polar solvent;

(b) forming a wet film from said wet matrix, said film having a top surface, a bottom surface and a depth between said top and bottom surfaces; and

(c) forming a self-supporting edible film by applying hot air currents to said film to dry said film, said dried film having a uniform distribution of said polymer and said solvent components, a uniform weight and a uniform thickness.

Claim 105 (new): The process according to claim 104, further comprising the step of adding an active component to said matrix of step (a).

Claim 106 (new): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) providing a wet matrix having a uniform distribution of edible components, said components comprising a polymer component and a polar solvent;

(b) forming a wet film from said wet matrix, said film having a top surface, a bottom surface and a depth between said top and bottom surfaces; and

(c) forming a self-supporting edible film by applying hot air currents to said film to initiate drying of the depth of said film prior to forming a polymer skin on said top surface of said film, said dried film having a uniform distribution of said polymer and said solvent components, a uniform weight and a uniform thickness.

Claim 107 (new): The process according to claim 106, further comprising the step of adding an active component to said matrix of step (a).

Claim 108 (new): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) providing a wet matrix having a uniform distribution of edible components, said components comprising a polymer component, an active component and a polar solvent;

- (b) forming a wet edible film from said wet matrix, said film having a top surface and a bottom surface; and
- (c) drying said film until said film is self-supporting by applying hot air currents to said film, wherein said air currents are applied to said bottom surface of said film at a velocity greater than to said top surface of said film.

Claim 109 (new): The process according to claim 108, wherein said air currents applied to said top surface of said film are less than that which cause surface rippling or skinning prior to drying of the depth of said film.

Claim 110 (new): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

- (a) providing a wet matrix having a uniform distribution of edible components, said components comprising a polymer component, an active component and a polar solvent;
- (b) forming a wet edible film from said wet matrix, said film having a top surface, a bottom surface and a depth of at least about 500 μm between said top and bottom surfaces; and
- (c) drying said film until said film is self-supporting by applying hot air currents to said film, wherein said air currents are less than that which cause surface rippling or skinning prior to drying of the depth of said film.

Claim 111 (new): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

- (a) providing a wet matrix having a uniform distribution of edible components, said components comprising a polymer component, an active component and a polar solvent;
- (b) forming a wet edible film from said wet matrix, said film having a top surface, a bottom surface and a depth between said top and bottom surfaces; and
- (c) drying said film by applying hot air currents to said film, wherein said dried film is self-supporting and said top surface of said dried film is non-rippled.

Claim 112 (new): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

- (a) combining and mixing an edible polymer component and a polar solvent to form an edible matrix with a uniform distribution of said components, wherein the mixing speed is controlled to reduce formation of air bubbles;
- (b) forming an edible film from said matrix, said film having a top surface and a bottom surface; and
- (c) drying said film from said bottom surface to said top surface by applying hot air currents to said bottom surface of said film until said film is self-supporting.

Claim 113 (new): The process according to claim 112, further comprising the step of adding an active component to said matrix of step (a).

Claim 114 (new): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

- (a) providing a wet matrix having a uniform distribution of edible components, said components comprising a polymer component and a polar solvent;
- (b) forming a wet edible film from said wet matrix, said film having a top surface, a bottom surface and a depth between said top and bottom surfaces; and
- (c) drying said film until said film is self-supporting by applying hot air currents to said film, wherein said air currents are insufficient to cause one or more of the following:
 - (i) surface skinning prior to drying the depth of said film;
 - (ii) surface rippling;
 - (iii) self-aggregation of components;
 - (iv) non-uniformity in the thickness of said film; and
 - (v) non-uniformity of mass per unit volume.

Claim 115 (new): The process according to claim 114, further comprising the step of adding an active component to said matrix of step (a).

Claim 116 (new): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

- (a) combining and mixing an edible polymer component, an edible active component and a polar solvent;
- (b) adding an anti-foaming agent to release oxygen from said mixture of components;
- (c) forming a wet edible film from said mixture of components;
- (c) providing a surface having top and bottom sides;
- (d) feeding said wet film onto said top side of said surface; and
- (e) forming a dried, self-supporting edible film having a uniform distribution of components by directing hot air currents at said bottom side of said surface.

Claim 117 (new): A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

- (a) combining an edible polymer component and a polar solvent to form an edible matrix with a uniform distribution of said components;
- (b) forming a wet film from said matrix;
- (c) providing a surface having top and bottom sides;
- (d) feeding said film onto said top side of said surface;
- (e) forming a self-supporting edible film by applying hot air currents to said bottom side of said surface with substantially no top air flow to dry said film; and
- (f) removing said self-supporting film from said surface.

Claim 118 (new): The process according to claim 117, further comprising the step of adding an active component to said matrix of step (a).